

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

**CHARLESTON DIVISION**

<b>IN RE: BOSTON SCIENTIFIC CORP., PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02326 MDL 2326  JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>
<b>THIS DOCUMENT RELATES TO THE FOLLOWING CASES:</b>	
<i>All Cases</i>	<b>Wave 4</b>

**PLAINTIFFS' REPLY IN SUPPORT OF THEIR MOTION TO EXCLUDE  
THE OPINIONS AND TESTIMONY OF STEPHEN H. SPIEGELBERG, PH.D.**

**I. INTRODUCTION**

Defendant Boston Scientific Corporation (“BSC”) doubles down on its attempt to convert a chemical engineer – Mr. Stephen H. Spiegelberg, Ph.D. (“Dr. Spiegelberg”) – into an industry standards expert like Dr. Peggy Pence, Ph.D. *See* BSC’s Resp. Opp. Pls.’ Mot. Exclude Ops. & Test. Dr. Stephen Spiegelberg, Ph.D., 2-4, Oct. 25, 2018, ECF No. 7088 [hereinafter BSC Resp.]. In addition, *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) bars Dr. Spiegelberg’s new scientific literature opinions that he bases on three (3) recent publications because Dr. Spiegelberg neglected to account for new articles that refute his opinions. *See* Exhibit 1, Supplemental Expert Report of Stephen Spiegelberg, at 1-4 (Apr. 11, 2018) (“Wave 4 Report”). Because *Daubert* bars the testimony Dr. Spiegelberg proffers in the Wave 4 Report, this Court should grant the Plaintiffs’ motion.

## **II. ARGUMENT & AUTHORITIES**

### **A. Dr. Spiegelberg's *Iipse Dixit* Method And Inadequate Qualifications Preclude His Opinions On Industry Standards.**

To testify as an expert, a witness must be “qualified . . . by knowledge, skill, experience, training or education” Fed. R. Evid. 702. Regulatory or industry opinions without *any* “authority” or “ascertainable ‘standards’ to govern the expert’s methodology” amount to *ipse dixit* opinions that “fall short of *Daubert*’s reliability prong.” *Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 697 (S.D.W. Va. 2014) (quoting *Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at \*35 (S.D.W. Va. Sept. 29, 2014) (quoting *Daubert*, 509 U.S. at 594)).

Here, BSC attempts to expand Dr. Spiegelberg into an industry expert on the entire design and testing process for medical devices based on this Court’s prior rulings. BSC Resp. at 3. However, Dr. Spiegelberg’s qualifications only permit him “to opine on ISO standards.” *In re Boston Sci. Corp. Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2326, 2018 WL 2440282, at \*3 (S.D.W. Va. May 30, 2018). Because *Daubert* only allows Dr. Spiegelberg to testify about ISO standards, the Court should grant the Plaintiffs’ motion and limit Dr. Spiegelberg’s opinions.

### **B. The Court Must Exclude Dr. Spiegelberg’s Testimony On The Wave 4 Report Because The Opinions Resulted From An Unreliable Method.**

As BSC argues in this MDL, an expert’s opinion is “unreliable if he fails to account for contrary scientific literature and instead ‘selectively [chooses] his support from the scientific landscape.’” *Eghnayem*, 57 F. Supp. 3d at 676 (quoting *In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005)). “[I]f the relevant scientific literature contains evidence tending to refute the expert’s theory and the expert does not acknowledge or account for that evidence, the expert’s opinion is unreliable.” *Id.* at 676-77 (quoting *In re Rezulin Prods. Liab. Litig.*, 369 F.Supp.2d at 425).

Here, Dr. Spiegelberg only relies on three (3) studies published since 2016 in reaching the

opinions in his Wave 4 Report. *See* Ex. 1, Wave 4 Report at 1 n.1, 3 n.3, 5. Although BSC's response attempts this into a discussion on Dr. Mays, the issue here involves Dr. Spiegelberg and his bases for the opinions in his Wave 4 Report. In his report, Dr. Spiegelberg neglected to ***acknowledge or account*** for *Thompson* (2017)<sup>1</sup> – a study that criticized the cleaning methodology in the *Thames* (2016) study. *See generally* Ex. 1, Wave 4 Report. In addition, Dr. Spiegelberg failed to otherwise ***acknowledge or account*** for any other literature refuting his opinions in the Wave 4 Report. *See generally id.* Because Dr. Spiegelberg neglected to “acknowledge or account” for “scientific literature” that “refute[s] [Dr. Spiegelberg]’s theory,” “[Dr. Spiegelberg]’s opinion is unreliable.” *See Eghnayem*, 57 F. Supp. 3d at 676 (quoting *In re Rezulin Prods. Liab. Litig.*, 369 F.Supp.2d 398, 425 (S.D.N.Y. 2005)). The Court should therefore exclude the opinions in Dr. Spiegelberg’s Wave 4 Report.

### **III. CONCLUSION & PRAYER**

For these reasons, Dr. Spiegelberg’s proposed testimony in the Wave 4 Report should be excluded in its entirety.

Dated: November 1, 2018

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<sup>1</sup> Margaret Thompson et al., *In Vivo Polypropylene Mesh Degradation is Hardly a Myth*, 28(2) INT. UROGYNECOL. J. 333-335 (2017).

**CERTIFICATE OF SERVICE**

I hereby certify that on November 1, 2018, I electronically filed the foregoing Motion to Exclude with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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